



PROFESSIONAL MEDICAL PRODUCTS

- **Apparecchio per test pediatrico uditivo**
 - **Paediatric hearing test device**
- **Appareil pour test pédiatrique auditif**
- **Aparato para test pediátrico auditivo**



Pediatric hearing test device

Instructions for use

⚠ This hearing screening device is intended for preliminary analysis of the audiometric response in children aged 6 months and older.

Intended use:

The device is a small instrument helping parents to have general indications about the child's response.

⚠ **Indication:** The pediatric hearing testing device is a small electronic instrument for evaluating the response to sound stimulus in children aged 6 to 10 months (this does not mean that it cannot be used also for older children). The two sounds used were calibrated on frequencies and intensities to produce a high-pitched tone (pressing the T2 button) and a low-pitched tone (pressing the T1 button).

If there is no response, please contact your doctor.
Contraindications: There are no known contraindications.
Improper use. The device's structure must not be modified. This could lead to erroneous results, safety risks and damage to the device.

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The device must only be used according to the instructions given.

Warranty. The warranty is void when:

- the indications in the instructions for use are not followed
- it is not used in compliance with the described uses
- changes are made or the device is opened
- there is damage of mechanical origin and damage due to the environment, liquids and normal wear and tear
- there is inappropriate positioning or structure.

Keep within a temperature range of -5°C/50°C and use in a temperature range of 10°C/40°C. Keep away from heat sources.

Before using, carefully read the instructions for use.
Safety indications. Pay attention to the instructions.

- Only use batteries identical to those supplied (L1028 23A)
- Do not invert the polarity of the batteries when replacing.
- Do not use in the presence of flammable anaesthetic mixtures.

Delivery inspection. Check the packaging upon delivery and when unpacking the device make sure there is no visible external damage.

Use. The test is easy to perform and is done following the BOEL test method (look towards sound), by getting the child interested in an object that they can play with and distracting their attention from the people around them. Then the above mentioned sounds are made alternately in various areas (on the left and right, high and low, at a distance of about 20 cm from the patient's ear) observing whether the child responds by turning towards the sound. The compactness of the device and its shape make it easy to use since they allow:

- it to be hidden in the palm of the hand so that child is only attracted by the sound of

the device,
- it to be held in either the right hand (pressing the button with the index and middle fingers) or the left hand (using the thumb instead) without obstructing the small hole in the centre of the device where the sound is emitted.

If the child responds to this stimulus by turning his/her head and focusing, the test is considered positive. If not, it is best to repeat the test after a few weeks since a simple illness can affect the test.

Specifications. Frequencies: 125Hz; 5kHz (±2%). Amplitude: 86dBA; 96dBA.

Cleaning. Do not use harsh detergents (solvents and the like), just use a damp cloth. Do not immerse in water.

Disposal: The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment.

GIMA WARRANTY TERMS:
The Gima 12-month standard B2B warranty applies.

Distribuito da/Distributed by/Distribué par/Distribuido por
Gima S.p.A - Via Marconi, 1 - 20060 Gessate (MI) - Italy
gima@gimaitaly.com - export@gimaitaly.com
www.gimaitaly.com

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LEVETTA s.a.s. - Via dei Cancellieri, 6/8 - 51100 Pistoia **Made in Italy**

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